

At the interview, the rejection of claims 13-16 and 18 under 35 USC §112, first paragraph as containing subject matter that was not described in the specification at the time the application was filed was discussed. The undersigned agent emphasized that claims 13-16 are fully supported by the present specification. It was noted that the Examiner is correct in considering that the claimed method includes:

- 1) integrating a transgene in a plant that has been previously rendered male sterile, or

- 2) integrating a construct that carries both the transgene of interest in the gene of artificial male sterility (AMS).

However, the present specification fully supports integrating a transgene in a plant that has been previously rendered male sterile. Examiner Kubelik's attention was respectfully directed to the specification of the present application which provides "Preferably, in accordance with the invention, the said plant can have been rendered male-sterile by genome, of a sequence which comprises an AMS gene and the said transgene of interest, with these genes being genetically linked" (present specification page 3, lines 9-14). It was emphasized that "preferably" indicates the specification implies that there are other ways of integrating the transgene in a plant already male sterile.

As further evidence of this assertion, the Examiner's attention was also respectfully directed to page 6, lines 32-35 of the present specification which states, "or transforming plant cells which carry a cytoplasmic or nuclear male sterility so as to integrate a transgene of interest into the genome of these cells". As noted in the interview summary, it is believed that it was agreed that claims 13-16 and 18 are fully supported by the present specification.

At the interview, the rejection of claims 13-16 and 18 as allegedly being unpatentable over PAUL et al. in view of ELLSTRAND et al. and NYERS et al. was also discussed. Furthermore, the rejection of claims 13-16 and 18 as being allegedly unpatentable over WORRALL et al. in view of ELLSTRAND et al. and NYERS et al. was also addressed. A declaration by Pascaul Perez was submitted to Examiner Kubelik as evidence of the non-obviousness of the claimed invention. As the declaration was a fax copy, Examiner Kubelik encouraged the submission of a clean copy of the declaration.

As such, the executed declaration of Pascual PEREZ attesting to the non-obviousness of the present invention is enclosed with this amendment.

As noted in the interview, Applicants traverse the rejection of claims 13-16 and 18 as allegedly being unpatentable over FABIJANSKI et al. 5,728,558 in view of ELLSTRAND and NYERS et al.

FABIJANSKI et al. is directed to a process for producing hybrid seed using male sterile plants created by employing molecular techniques to manipulate antisense genes and other genes that are capable of controlling the production of pollen in plants. While FABIJANSKI et al. describes the use of male sterility for seed production, FABIJANSKI et al. fails to disclose using male sterile plants for preventing transgene escape.

In an effort to remedy the deficiencies of FABIJANSKI et al., the Official Action combines the ELLSTRAND et al. and NYERS et al. publications with FABIJANSKI et al. However, ELLSTRAND et al. and NYERS et al. also fail to use male sterility plants to prevent transgene dissemination.

NYERS et al. is directed to a review of the progress for the production and use of sterile trees. However, NYERS et al. fails to use male sterile trees to prevent transgene dissemination. ELLSTRAND et al. also fails to use male sterile trees to prevent transgene dissemination.

ELLSTRAND et al. places a clear limitation as to the application of male sterility in plants. In fact, ELLSTRAND et al. emphasizes that male sterility could be put into practice "if the product is not a seed or fruit" (page 439, right column, lines 14-16).

As the Examiner is aware, to establish a *prima facie* case of obviousness, ~~three basic criteria must be met.~~ First,

there must be some suggestion or motivation, either in the references themselves or knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claim limitations. A teaching or suggestion to make the claim combination and a reasonable expectation of success must both be found in the prior art and not based on Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ 2d, 1438 (Fed Cir. 1991).

The references cited all fail to actually use male sterility to prevent transgene dissemination. At best, FABIJANSKI et al., ELLSTRAND et al. and NYERS et al. allude to the fact that male sterility may be a vehicle for preventing transgene dissemination. However, as the cited references actually fail to disclose the necessary steps in accomplishing the invention of transgene dissemination via male sterility, one of ordinary skill in the art would lack a reasonable expectation of success that the use of male sterility would ensure an efficient prevention of transgene escape.

Claims 13-16 and 18 were also rejected for allegedly being unpatentable over WORRALL et al. in view of ELLSTRAND et al. and NYERS et al. This rejection is also respectfully traversed for the reasons noted above.

WORRALL et al. is directed to causing male sterility in transgenic tobacco. WORRALL et al. describe the use of a gene system to achieve nuclear male sterility in tobacco, but WORRALL et al. fail to teach the use of such a system to prevent transgene dissemination.

As noted above, ELLSTRAND et al. is a general review about the risk of engineered genes escaping through hybridization. NYERS et al. mentions the use of genetic sterility as a way to prevent transgenes from entering natural gene pools. However, ELLSTRAND et al. and NYERS et al. fail to disclose any further information about the way to put such a strategy into practice. The publications fail to provide any evidence of controlling transgene escape.

Nevertheless, even if one of ordinary skill in the art might have been motivated to combine any of the cited publications of FABIJANSKI et al., WORRALL et al., ELLSTRAND et al. or NYERS et al. alone or in combination to attempt the use of nuclear male sterility to avoid transgene escape, the publications fail to provide any evidence that this strategy would actually be successful.

It is respectfully submitted that the proposed combinations of references set forth in items 11 and 12 of the outstanding Official Action fail to render obvious the claimed invention. One of ordinary skill in the art would lack a

reasonable expectation of success of obtaining the present invention.

Therefore, it is respectfully submitted that the alleged obviousness rejection set forth in the outstanding Official Action constitutes at best a suggestion that it might be "obvious to try" a method of the claimed invention. The Examiner's attention is respectfully directed to the case of *In re Dow Chemical*, 5 USPQ 2d 1529, 1531 (Fed Cir. 1988), wherein it was held:

"The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in light of the prior art... both the suggestion and the expectation of success must be found in the prior art, not in the Applicant's disclosure. (citations omitted)."

Thus, it is respectfully submitted that the proposed combinations of cited publications of the outstanding Official Action would have failed to render obvious the presently claimed invention.

In view of the present amendment and the foregoing remarks, therefore, it is believed that this application has been placed in condition for allowance. Allowance and passage to issue on that basis are accordingly respectfully requested.

PEREZ et al. S.N. 09/380,086

Attached hereto is a marked-up version of the changes made to the claims. The attached page is captioned "VERSION WITH MARKINGS TO HOW CHANGES MADE."

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Claim 16 has been amended as follows:

--16. (amended) The method according to claim 13, wherein said plant contains an artificial male sterility (AMS) gene conferring said male sterility.--